DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 19, 2014

Lightlab Imaging, Inc.
Jeffrey Roberts
Principal Regulatory Affairs Specialist
4 Robbins Road
Westford, Massachusetts 01886

Re: K141453
Trade/Device Name: Ilumien Optis, Dragonfly Optis Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, NQQ
Dated: August 7, 2014
Received: August 8, 2014

Dear Jeffrey Roberts,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ken Skodacek for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: ILUMIEN OPTIS

Indications for Use:

The ILUMIEN OPTIS with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The ILUMIEN OPTIS will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

Prescription Use __X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(K) SUMMARY

for the LightLab Imaging, Inc.
ILUMIEN OPTIS
and
Dragonfly OPTIS Imaging Catheter
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

LightLab Imaging, Inc.
4 Robbins Road
Westford, MA 01886

Contact Person: Jeffrey Roberts
Telephone: 978-577-3451

Date Prepared: 5/30/14

2. DEVICE NAME

Proprietary Name:	ILUMIEN OPTIS
Common/Usual Name:	Ultrasonic pulsed echo imaging system
Classification Name:	Ultrasonic pulsed echo imaging system

Proprietary Name:	The Dragonfly OPTIS Imaging Catheter
Common/Usual Name:	Diagnostic Intravascular Catheter
Classification Name:	Diagnostic Intravascular Catheter

3. DEVICE CLASSIFICATION

The ILUMIEN OPTIS medical device comprises the following:

Classification Name	Ultrasonic Pulsed Echo Imaging System
Classification Regulation	21 CFR 892.1560
Product Code	NQQ

The Dragonfly OPTIS Imaging Catheter device comprises the following:

Classification Name:	Diagnostic Intravascular Catheter
Classification Regulation:	21 CFR 870.1200
Product Code:	DQO

4. PREDICATE DEVICE

- ILUMIEN OPTIS with Dragonfly I Catheter manufactured by LightLab Imaging, Inc. K123369

5. DEVICE DESCRIPTION

The ILUMIEN OPTIS is a cart-mounted computer and Imaging Engine (or optical engine) placed inside an ergonomically designed mobile cart. It also includes the Drive-motor and Optical Coupler (DOC), which provides the interconnection between the ILUMIEN OPTIS System and the Dragonfly Catheter. The cart is equipped with two display monitors (one for the console operator, and the other for the physician), as well as a keyboard and mouse. The cart also contains an isolation transformer for electrical safety. The cart includes two USB mounted FFR receivers which provide wireless reception of distal intracoronary and aortic pressure signals originating at the PressureWire® Aeris and the aortic pressure transducer (AIU). These signals are used to calculate and display the patient's Fractional Flow Reserve (FFR) on the system monitor.

The Dragonfly OPTIS Imaging Catheter is a sterile, single-use intravascular catheter consisting of a catheter body external sheath and an internal rotating fiber optic imaging core. The external sheath serves two primary functions: 1) to facilitate placement of the device into the coronary artery and 2) to cover and protect the inner rotating fiber optic imaging core.

The inner rotating fiber optic imaging core emits near infrared light to the tissue and receives reflected light. It is driven by a stainless steel torque wire visible under fluoroscopy and pulled back through the window tube of the external sheath by the DOC. The emitted and returned reflected light are combined and processed by the Ilumien Optis System software to construct an OCT image. The patient is never exposed to moving parts as the external sheath completely covers the rotating imaging core.

6. INTENDED USE

The ILUMIEN OPTIS with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The ILUMIEN OPTIS will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

ILUMIEN OPTIS

The ILUMIEN OPTIS is equivalent to the predicate device in terms of hardware and firmware components. They both contain a DOC which provides the interconnection between the ILUMIEN OPTIS and the optical imaging catheters that emit near-infrared light to produce high-resolution real-time images. This process is accomplished for both the ILUMIEN OPTIS and the predicate device through a graphical user interface (GUI) and software control to obtain Optical Coherence Tomography (OCT) imaging modality and fractional flow reserve (FFR) measurements.

The ILUMIEN OPTIS represents an upgrade to the predicate device in terms of performance through the same hardware and firmware design and technological characteristics. The software has been upgraded to revision E.1 for the following features:

- A curtain GUI interface.
- Dragonfly OPTIS Imaging Catheter Support
- Continuous calibration for TiO_2 doped catheter window
- DICOM modality integration
- Manual pull back triggering
- Catheter user connection interface
- Improved acquisition workflow display

Dragonfly OPTIS Imaging Catheter

The Dragonfly OPTIS Imaging Catheter is equivalent to the predicate device in terms of hardware components and operational use. They both are comprised of a catheter body external sheath and internal rotating fiber optic imaging core which emits near infrared light to the tissue and receives reflected light. They both are driven by a stainless steel torque wire by the DOC which is connected to the ILUMIEN OPTIS OCT Imaging System. They are both purged through the central catheter with 100% contrast media prior to use. In both the Dragonfly OPTIS Imaging Catheter and the predate device emitted and returned reflected light are combined and processed by the ILUMIEN OPTIS software to construct an OCT image.

The Dragonfly OPTIS Imaging Catheter represents an upgrade to the predicate device in terms of performance through the same operational characteristics, and fundamental technological characteristics to include the following:

- TiO_2 Doped window
- Flexible proximal end
- Improved break away joint
- Improved purge tube
- Dual lumen tip
- High speed proximal end
- 155µm fiber
- RFID.

8. PERFORMANCE TESTING

The ILLUMIEN OPTIS has been tested and is in compliance with UL Standard No 60601-1, Medical Electrical Equipment Part I: General Requirements for Safety, IEC 60601-1-2 Ed. 2.1, Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment, EN 60601-1-2:2007, Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment, IEC 60825-1, 2nd, Ed., 2007, SAFETY OF LASER PRODUCTS – Part 1: Equipment classification and requirements, DICOM Standard (PS 3.2-2008), 21 CFR 1040.10, Performance Standards for Light-Emitting Products, Laser Products, and CFR 47 FCC Part 15 Subpart B Class B emissions requirements (USA)

In addition to the electrical safety testing performed, software verification and validation was conducted to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met these requirements. Design verification and

validation was also performed on the ILUMIEN OPTIS and Dragonfly OPTIS Imaging Catheter in compliance with internal design control procedures which included bench testing and pre-clinical animal testing. The results of this testing concludes the ILUMIEN OPTIS and Dragonfly OPTIS Imaging Catheter is determined to be safe and effective and is substantially equivalent to the predicate ILUMIEN OPTIS device.